Congress of the United States
Washington, DC 20515

March 27, 2020

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: Docket ID: EPA-HQ-OAR-2018-0746
Docket ID: EPA-HQ-OAR-2019-0178

Dear Administrator Wheeler:

We write as members of the bipartisan Congressional Ethylene Oxide Task Force and speak for the tens of thousands of our constituents who live within a few miles of facilities that use ethylene oxide (EtO). This letter serves as our comment on two prospective Environmental Protection Agency (EPA) rules being considered for EtO, the Miscellaneous Organic Chemical Manufacturing rule and the commercial sterilizer rule. We believe that any rules issued by EPA regarding the safe use of EtO must include consideration of the following concerns:

I. The first priority of any rule, in both substance and process, must be assuring the people in neighboring communities that the air they breathe is safe

As a Task Force, we have met with our constituents, the medical sterilization industry, and local officials to discuss how we can work together to address EtO. While these different groups of stakeholders have not always agreed, there was universal sentiment that EPA has not been fulfilling its obligations to engage with these local communities.

EPA's inaction and missteps have stoked very real fears, anxiety, and confusion felt by our constituents—from mayors and school boards to parents and pastors. Beyond regulation of EtO, central to EPA's role is clearly and effectively communicating the risk of EtO poses to neighboring communities, and right now our constituents feel left in the dark. We have expressed deep frustration with EPA's lack of engagement subsequent to the 2016 reclassification of EtO and made it clear that we expect EPA to do a much better job communicating on the risks of EtO. That means working with communities to gather more data on the air they breathe, to communicate with local leaders and stakeholders about the risk of EtO, and to engage directly with Congress.

As the EPA works through the process of these rules, we implore the Agency to be thinking about how to effectively communicate with the public every step of the way. And we believe that the health and safety of our constituents must be the foundation on which these rules are built.

II. Only ambient air monitoring—not computer modeling—provides a full and complete understanding of local and national EtO levels and is vital to an informed rulemaking

In our repeated attempts to get EPA to conduct ambient air monitoring in our communities to measure EtO levels, the Agency has regularly said it is relying on computer modeling to determine ambient levels of EtO. The accuracy of computer modeling runs contrary to the experience of our communities.

In Willowbrook, Illinois, EPA-funded air monitoring demonstrated that fugitive emissions of EtO were far more pervasive and significant source of community exposure. Such fugitive emissions, identified by ambient air monitoring, were central to the public health threat that community faced. This is why ambient air monitoring is vital to the integrity of any rule.

By EPA's own admission, when the Agency conducts computer models of ambient EtO, it must input assumptions for what it expects fugitive levels to be. We firmly believe the EPA cannot fully account for fugitive emissions without first conducting ambient air monitoring. As the experience of Willowbrook demonstrates, EPA cannot rely on self-reported stacks emissions data from EtO facilities. The only way to provide neighboring communities the assurance they deserve is to conduct ambient air monitoring. Only ambient air monitoring will fully put to rest our constituents' concerns. This is why ambient air monitoring is vital to the integrity of any rule.

We have discussed with EPA the lack of data on national background levels of EtO. While we appreciate EPA's work through its national monitoring network to fill the gaps in our understanding of national EtO background levels, we believe there is still much data needed to fully grasp the issue. The National Air Toxic Assessment brought to light the scale of EtO emissions nationally, and we must conduct a similarly comprehensive assessment to best understand national background levels. Only once we fully understand national background levels can we begin to assess what might constitute safe ambient levels. This is why ambient air monitoring is vital to the integrity of any rule.

III. Reassessing the IRIS value for EtO would come at great expense to the credibility of EPA and would not be well-founded without additional data

In its comment letters to EPA, the sterilization industry stated its belief that the Agency must reevaluate the Integrated Risk Information System (IRIS) value for EtO. We do not share this belief.

We recognize the need to build upon the IRIS value, both because we lack a full understanding of national background levels and because the IRIS value is largely based on occupational exposure—not the ambient exposure our constituents face. We must have an IRIS value that the public can have faith in and that is informed by science. However, EPA's disengaged approach has severely undercut the Agency's credibility on EtO.

If EPA were to fundamentally change the IRIS value without additional data and due diligence, it would completely undermine public faith in a process that is supposed to inform public health and safety. We firmly believe that without additional ambient air monitoring around facilities that use EtO—locally-collected air data and not just industry-provided stacks data—EPA will not have a sufficiently informed rule, nor would it be in a position to adjust the IRIS value for EtO.

IV. Any rule must reflect the diversity of industrial facilities, cannot be one-size-fits-all, and the EPA must assist small businesses with compliance

As EPA works through its rulemaking process, we encourage and expect the agency to take into account the diversity of the sterilization industry. We have heard from industry concerns that any one-size-fits-all approach would not take into account the unique nature of each sterilization facility. This is especially the case given the pervasiveness of fugitive emissions – each facility is going to have its own unique challenges to contain fugitive EtO.

Similarly, the EPA must work to help small businesses comply with the prospective regulations. We are encouraged by the agency convening a Small Business Advocacy Review Panel, especially given how many sterilizers are considered small businesses. As the EPA understands the unique challenges small businesses face, we encourage you to work with Congress to develop resources for these small businesses to achieve the overall standard—and not to pursue specific exemptions on emissions for small businesses. We need to work together bringing all actors up to the same strong standard.

Thank you for your consideration of our concerns. We appreciate the opportunity to discussing them in greater detail when we meet you in person on March 31. We look forward to working together on this issue – please do not hesitate to reach out to us as a resource in communicating the work EPA is doing. Should you have any questions, please contact Tommy Brown (tommy.brown@mail.house.gov) in Rep. Schneider's office and Kaitlyn Dwyer (kaitlyn.dwyer@mail.house.gov) in Rep. Hice's office.

Sincerely,

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